Attachment B: Literature Review

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Abu-Elmagd K, Reyes J, Todo S, et al. / Clinical intestinal transplantation: new perspectives and immunologic considerations / American College of Surgeons / 1998	case review/ partially controlled retrospectively	survival and complications, nutritional conversion. Acute rejection was diagnosed by histopathologic studies of random endoscopically guided multiple mucosal biopsies, usually of the illuem. Suspicious skin or gastrointestinal lesions were biopsied for GVHD.	98 consecutive patients (59 children and 39 adults) received 104 allografts. 37 SB alone, 50 SB/L, and 17 MV. Short gut syndrome was the most common (N=78), with at variety of causes; predominately thrombotic disorders, Crohn's disease and trauma in adults and mostly volvulus, gastroschisis, necrotizing enterocolitis and intestinal atresia in children. Inclusion of the colon was abandoned after 1994 because it appeared to increase mortality.	12 recipients (3 SB alone, 9 composite grafts) are alive with good nutrition beyond the 5-year milestone. 47 (48%) of the total group survive bearing graft that provide full (91%) or partial (9%) nutrition. Actuarial patient survival at 1 and 5 years was 72% and 48%. Loss rate due to rejection was greater in SB alone. The best results were in patients between 2 and 18 years of age. Adjunct bone marrow did not significantly affect the incidence of graft rejection, B-cell lymphoma, or the rate of severity of GVHD. Resumption of oral diet was later in composite graft recipients than in those receiving SB alone. 91% (42 of 47) current survivors are home and completely off TPN with full nutritional autonomy. Of the 7 recipients who were censored following graft enterectomy, 5 died of TPN-related complications and 2 are at home on TPN.	Controlled for adjunct donor bone marrow cells.

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Abu-Elmagd KM, Reyes J, Fung JJ / Clinical intestinal transplantation: recent advances and future considerations / AST Primer on Transplantation /	Opinion			Outlines the current indication and describe new technical modification and recent advances in perioperative management of intestinal transplantation using the Pittsburgh and worldwide experience.	
Abu-Elmagd KM, Reyes JD, Mazariegos GV, et al / Intestinal transplantation / / 2000	Abstract			Results at Pittsburgh from 1990 - 1999. Acturial survival for 135 patients was 72% at 1-year, and 48% at 5 years with graft survival of 64% and 40% respectively. 95% survival are free of TPN. Survival best in patients between 2 - 18 years of age.	
Abu-Elmagd, K. / Proposal - medicare coverage of intestinal transplantation (request for formal review) / / 1999	Request for HCFA review				Arthur hopes to demonstrate to HCFA that transplantation of the intestine-only should be considered as a therapeutic option and part of the standard treatment that should be offered to patients w/ irreversible intestinal failure (specifically those who can't be maintained on TPN).

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Abu-Elmagd, K.M., Reyes, J., Fung, J.J., et al / Evolution of clinical intestinal transplantation: improved outcome and cost effectiveness / Transplantation Proceedings / 1999	case review	Survival - see results 51 (93%) of 55 current survivors are home, fully active and completely off TPN w/ full nutritional autonomy	115 intestinal transplantations in 109 patients. Transplants occurred over 8 yrs. 64(59%) were children and 45(41%) were adults. Causes of intestinal failure: short gut syndrome (SGS) in 89 (81%), dysmotility syndrome in 11 (10%), intestinal neoplasm in 6 (6%), and enterocyte in 3 (3%). The intestine was engrafted alone (n=43) or as part of a composite graft (n=72).	Survival: overall cumulative 72% at 1 yr. And 48% at 5yrs w/ graft survival 64% and 40%. Survival benefits of intestinal transplantation were better for children, particularly for those 2-17 yrs for whom the 5yr survival was 68%. Graft loss from rejection was significant among the isolated intestine (P=.045). The best survival rates for adults were amongst those w/ Crohn's disease and vascular thrombosis.	* survival benefits were best for children, which needs to be considered in coverage for Medicare beneficiaries *patient characteristics/selection should be further reviewed in the previous articles mentioned. *Of the patients who are at home, completely off TPN, how many of them are adults and how many are children?
Bertinet DB, Tinivella M, Balzola FA, et al / Brain manganese deposition and blood levels in patient undergoing home parenteral nutrition / Journal of Parenteral and Enteral Nutrition / 2000	Logitudinal study	whole-blood, plasma, intra-erythrocytes, and urinary Mn concentrations were measured and brain magnetic resonance was performed at the beginning and after 1 year.	15 patients undergoing TPN, median duration 3.8 years. No patients showed psychosis, extrapyramidal syndrome, or cholestasis.	At beginning 10 or 15 patients (67%) showed paramagnetic accumation on cerebral MRI. 1-year later there was a reduction of cerebral Mn accumulation. In all patients, blood-Mn levels were significantly reduced after 1-year of Mn intravenous supplementation withdrawal. Conclusion- that patients receiving long-term TPN showed elevated incidence of alteration in brain MRI with a median Mn intravenous supplementation of 0.1 mg/d.	

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Blue Cross Blue Shield Technology Evaluation Center / Small bowel transplants in adults and multivisceral transplants in adults and children / Assessment Program / 1999	assessment				
Burnes JU, O'Keefe SJ, Fleming R, et al / Home parenteral nutrition - a 3-year analysis of clinical and laboratory monitoring / Journal of Parenteral and Enteral Nutrition / 1992	Case series	3-year anlaysis (1986-1989). plasma chloride, glucose, alkaline, phosphatase, serum glutamic oxaloacetic transaminase, total protein, albumin, selenium, iron concentrations, calcium magnesium, vitamin C & D, creatinine	63 home TPN patients, 40 with short-bowel syndrome and 23 with chronic intestinal obstruction with or without intestinal resection.	73% had normochromic anemia. 42% had high blood creatinine associated with low urine volumes. 78% returned to relatively normal lifestyles.Overall mortality was low (5% per year), but 73% needed readmission to hospital, mainly for suspected catheter sepsis. Problems with chronic fluid, electrolyte and micronutrient deficiencies, catheter sepsis, and insurance coverage often restrict optimal rehabilitation.	

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Cavicchi M, Beau P, Crenn P, Degott C, Messing B / Prevalence of liver disease and contributing factors in patients receiving home parenteral nutrition for permanent intestinal failure / Annals of Internal Medicine / 2000	Prospective cohort study	Kaplan-Meier method used to determine the acturial occurrence of chronic cholestasis and complicated TPN-related liver disease (bilirubin level, factor V, portal hypertension, encephalopathy, ascites, gastrointestinal bleeding, or histologically proven extensive fibrosis or cirrhosis). Contributing factors were assessed by using univariate and multivariate (cox) analysis.	90 patients with permanent intestinal failure who were receiving PN enrolled from 1985-1996	58 patients (65%) developed chronic cholesrasis after a median of 6 months and 37 (41.5%) developed complicated TPN-related liver disease after a median of 17 months. Of these patients, 17 showed extensive fibrosis after 26 months and 5 had cirrhosis after 37 months. The prevalence of complicated TPN-related liver disease was 26% +-9% at 2 years and 50% +- 13% at 6 years. In multivariate analysis, chronic cholestasis was significantly associated with a TPN-indipendent risk for liver disease, a bowel remnant shorter than 50 cm. And a parenteral lipid intake of 1g/kg of body weight per day.	
Chatzipetrou MA, Tzakis AG, Pinna AD, et al / Intestinal transplantation for the treatment of desmoid tumors associated with familial adenomatous polposis / Unpublished /	Case series			9 patients with FAP and intestinal failure due to desmoid tumors were treated with intestinal transplantation (SBT, SB/LT, MVT). Desmoid tumors recurred in the abdominal wall of two patients. 2 patients died; 1 graft lost to severe rejection was replaced. 11 - 53 months after transplant, 7 patients were alive, well, independent of TPN	

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Deltz E, Schroeder P, Gebhardt H, etal. / Successful clinical small bowel transplantation: Report of a case / Clinical Transplantation / 1989	Single case study		42 year old woman. First successful SB transplant on 8/9/88 after 10 week of TPN. Living related donor (sister).	Oral intake on 9/9/88 first complete meal was allowed 14 days later. At 4 months post transplant, patient was in excellent clinical condition with constant body weight and tolerating 3-4 bowel movements of fluid stools and parenteral administration of CSA and steroids. Patients who are SMTP candidates should not be kept on TPN too long in order to avoid TPN induced liver damage.	Single case study. No long term outcomes studied. Early in the development of the procedure.
DiMartini A, Rovera GM, Graham TO, et al / Quality of life after small intestinal transplantation and among home parenteral nutrition patients / Journal of Parenteral and Enteral Nutrition / 1999	Cohort comparison	Responses on the Quality of Life Instrument - 130 questions to assess the impact of disease on health, behavior, and psychosocial adjustment	9 intestinal transplant patients, mean age 26.6, 6 women, 8 white, 5 single. Average pre-transplant TPN 31 months. Surveyed average 22 months post transplant. TPN cohort - 10 patients, mean age 37.4, 6 women, 9 white, 2 single, average TPN 50 months, 4 candidates for intestinal transplant.	The intestinal transplant patients reported significant improvement in the quality of their life and function. They rated the quality of life pre-transplant (TPN dependency) as worse than before developement of intestinal failure. The TN cohort report significant worsening across most areas of quality of life when compared to pre-morbid state.	
Farmer DG, McDiarmid SV, Yersiz H, et al / Improved outcome after intestinal transplantation: an 8-year, single center experience / unpublished /	Case series			This hospital selection criteria for intestinal transplantatio is irreversible TPN-associated liver disease, loss of vascular access, and severe line sepsis.	

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Furukawa H, Reyes J, Abu-Elmagd K, et al. / Intestinal transplantation at the University of Pittsburgh: six-year experience / Transplantation Proceedings / 1997	case review	Patient and graft survival and reasons for graft loss.	33 SB alone, 40 SB/L and 13 MV. 52 of 86 children. Patients were grouped by phases from earliest to most recent. Recipients randomly selected for phase 1 & 2; patients carefully selected in phase 3	Overall 1-year survival 73% and 2-year survival was 60%. 1-year survival by phase was 86.7% phase 1, 58.6% for phase 2 and 74.4% for phase 3. 3-year patient survival for phase 1 was 53.3%, and 34.5% for phase 2. 1 year graft survival was 80.7%, 43.8% and 71.5% for each of the respective phases. The major causes of graft loss were rejection, posttransplant lymphoproliferative disease and infection. 13 patients in phase 3 have received donor-derived simultaneous. While 1-year survival was better in these patients, the difference was not statistically significant. "Although effort may have allowed intestinal transplantation to reach a new stage of development, further efforts need to be made to improve intestinal function and to prevent intestinal rejection."	Case reviews are low in evidence hierarchy.

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Grant D / Intestinal transplantation: 1997 report of the international registry / Transplantation / 1999	Case series	graft and patient survival, stopped TPN	33 intestinal transplant programs provided data on 272 transplants in 260 patients who were transpalntaed on or before 2/28/97. Two-third of the patients were children. Short gut syndrome was the most common indication for transplantation. SBT, SB/LT, and MVT were represented.	The 1-year graft/patient survival for transplants performed after February 1995 was 55%/69% for SBT, 63%/66% for SB/LT, and 63%/63% for MVT. Transplants since 1991 and programs that had performed at least 10 transplants had significantly higher graft survival rates. 77% of current survivors had stopped TPN. The 5-year survial rate of intestinal transplantation with large series is comparable to lung transplantation.	

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Grant D, Wall W, Mimeault R, et al. / Successful small-bowel/liver transplantation / Lancet / 1990	case review	Screening for liver rejection included measurement of prothrombin times, biliruin concentrations, and liver enzymes. Intestinal allograft function was assessed by faecal fat excretion, D-xylose absorption, a Schilling test, an absorption of oral cyclosporin. Screening for intestinal rejection included examination of serial endoscopic stomal biopsy specimens and sequential measurement of intestinal permeability with chromium labeled edetic acid.	41 year old woman had short-gut syndrome. Thrombosis of her mesenteric artery led to infarction of the small intestine and necessitate removal of the distal duodenum, jejunum, and right colon. She remained hospitalized for 18 months due to intractable diarrhea, abdominal pain, recurrent pulmonary emboli, and repeated thrombosis of venous access sites. All peripheral access sites had become thrombosed.	Postoperative surgical complications included the development of intra-abdominal abscess, a Hickman catheter drainage infection, respiratory insufficiency, phrenic nerve palsy. Immunological complications included a tuncal rash and donor lymphocytes in blood but no chronic GVHD developed. No clinical or biochemical evidence of liver rejection. Enteral feeding was started a week after surgery and gradually increased in volume. Parenteral feeding was stopped 2 months post-transplant. Patient maintained normal weight on an unrestricted oral diet.	Single case review
Handelsman H, Zarin D / Small Bowel Transplantation / Center for Practice and Technology Assessment / 2000	Assessment				

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Howard L, Ament M, Fleming CR, Skike M, Steiger E / Current use and clinical outcome of home parenteral and enteral nutrition therapies in the United States / Gastroenterology / 1995	Case series		National Registry information collected on 9288 patients treated with TPN from 1985 to 1992.	There were approximately 40,000 TPN and 152,000 enteral home patients in 1992. The usage of TPN doubled between 1989 and 1992 and a large porportion was in patients with short survival. The prevalence of TPN in the U.S. was 4 - 10 times higher than in other Western countries. Outcome studies showed both therapies were relatively safe. The primary disease strongly influence survival and rehabilitation.	
Howard L, Hassan N / Home parenteral nutrition: 25 years later / Clinical Nutrition / 1998	opinion	Survival, catheter infection, metabolic complications		List of problems in TPN patient with auses and prevention suggestions	Does not explain methodology or data source
Idoate MA, Martinez AJ, Bueno J, Abu-Elmagd K, Reyes, J / The neuropathology of intestinal failure and small bowel transplantation / Acta Neuropathology / 1999	case comparison	Retrospective analysis of complete autopsy or brain biopsy specimens of 17 patients with intestinal failure. Neuropathological finding reported.	2 groups Group I included 5 adults and 8 children who had received intestinal transplantation. Group II were 4 children with intestinal failure who were candidates for SBT.	Central nervous system (CNS) disorders were reported in 92% of the transplant recipients and 100% of transplant candidates. CNS vascular, metabolic and infectious pathology are significant causes of morbidity and mortality in patients suffering intestinal failure, both before and after transplant. Brain atrophy was a frequent finding and may be related to nutritional and developmental inadequacy of long-term TPN.	

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Karatzas T, Khan F, Tzakis AG / Clinical intestinal transplantation : experience in Miami / Transplantation Proceedings / 1997	case review	Methods of immunsuppression, rejection episodes, survival	19 patients (11 children, 8 adults). 3 SB alone, 9 SB/L, and 7 MVT. All received bone marrow infusions from the donor.	Of the 6 patients transplanted between August 1994 and January 1995, 33.3% survived. 3 patients transplanted between 4/95 and 6/95 all alive but incidence of rejection was 2.0. 10 patients transplanted between 7/95 and 7/96 4 died.	No overall outcome computed. No discussion about quality of life and ability to ingest enterally.
Langnas AN / VI internation small bowel transplant symposium / Program syllabus / 1999	Abstracts				Collection of abstracts used in the symposium
Langnas AN, Dhawan A, Antonson DL, et al. / Intestinal transplantation in children / Transplantation Proceedings / 1996	Case Review	survival, length of stay, episodes of rejection, conversion to enteral nutrition	26 infants and children. Age range .75 to 10 years. Average age 2.5 years Treated at University of Nebraska Medical Center. 17 had combined liver/bowel transplants on patients with parenteral nutrition induced end stage liver disease. Nine other patients had failed TPN defined as early liver disease, limited central venous access, or complications related to TPN.	One year actuarial survival for liver/SBT is 65%. Cause of death included poor graft function, intestinal rejection, aspergillosis, adenovirus pneumonia, CMV enteritis and lymphoproliferative disease. All bowel TP alone were still alive. Time to enteral food conversion was 18 days for SBT alone and 45 days for MVTP. MVTP "is effective but has considerable morbidity and mortality. Isolated intestinal transplantation appears relatively safe and effective for select patients without end stage liver disease.	Review of cases at a single hospital. No control or comparison group.

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Langnas AN, Shaw BW, Antonson DL, et al. / Preliminary experience with intestinal transplantation in infants and children / Pediatrics / 1996	case reviews	Survival and complications. Enteric and surveillance biopsies 7 days post-op and when clinically indicated thereafter.	16 intestinal transplant of children at University of Nebraska Medical Center. 13 SB/L Nearly half of the patients were younger than 1 year. All but one had short bowel syndrome. All SB/L had TPN induced end-stage liver failure.	The 1-year actuarial patient and graft survival rates for recipients of SB/L were 76% and 61%. Six of 13 patients remaining alive are free of TPN. All 3 patients receiving SB alone are alive and TPN free at time of writing with mean length of follow-up 384 days. Major complications have included severe infections and rejection. Pre-operative location of patients (ICU, hospital home) did not seem to affect outcome strongly. In 2 SB/L patients SB grafts had to be removed because of rejections and enteritis caused by CMV. Infectious post-op complications were common, and mortality was universally the result of infectious complications. Once a patient leaves the hospital, fluid and electrolyte problems predominate the clinical course. SB/L seems to be a reasonable option for children facing impending death from end-stage liver disease caused by TPN.	small sample size (16). Not Medicare patient population
Misra S, Kirby DF / Micronutrient and trace element monitoirng in adult nutrition support / Nutrition in Clinical Practice / 2000	Opinion			Reviews the important micronutrient and trace elements relevant to nutrition support and offers monitoring suggestions for clinical practice.	

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Niv, Y., Mor, E., Tzakis, A. / Small bowel transplantation - a clinical review / The American Journal of Gastroenterology / 1999	case review	Briefly reviewed 5 observational studies of graft and patient survival after small bowel transplantation. Looked at 1,3 and 5 year survival.		Due to new immunosuppressive drugs, there have been great advances in survival, however, for small bowel transplantation to replace TPN, the survival needs to be even better for both patient and graft. The two main factors that affect long-term outcome are: preoperative status and the presence of sever acute rejection. Better drugs and better patient selection are needed.	
no author listed / Intestinal transplant registry / / 1999	Intestinal transplant registry			* centers that have performed more than 10 transplants have significantly lower peri-operative mortality rates *by six months, most intestinal recipients are free of TPN *during the first five years after transplantation, there is an ongoing decline in survival (graft & patient) due to graft rejection and complications due to immune suppression.	Supported by an educational grant from Fujisawa, Canada, Inc. Database (preliminary analysis) which includes: # of intestinal transplants, participating centers (world-wide), types of immunosuppressive drugs, indications in children/adults, pre-transplant status, factors affecting graft and patient survival, etc.

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O'Keefe SJ, Peterson ME, Fleming CR / Octreotide as an adjunct to home parenteral nutrition in the management of permanent end-jejunostomy syndrome / Journal of Parenteral and Enteral Nutrition / 1994	Case series	stomal output rates, gastric and pancreatic secretions, gut transit, stool and urine, hormonal assay	10 adult patients with adapted EJS. Reasons for intestinal loss and length of remaining small intestin varied. All patients had had ample time (greater than 1 year) to adapt to the loss of intestine. Nutritional status was normal in all but one patients. All patients were cautioned against excessive consumption of food and fluids, but no specific restrictions were made. Dietary analysis indicated caloric intakes 140%-334% of reting energy requirements. An 8-day adaption period was used to reestablish pre-study elecctrolye balance. Octreotide therapy was commenced as subcutaneous injections one half hour before each meal	After 10-days of treatment, significant reductions in stomal fluid and electrolyte losses (from 8.1 to 4.8), sodium (from 510 to 340), chloride (from 533 to 315), potassium (from 101 to 79) permitting an average reduction in intravenous fluid requirements of 1.3 L/d. This meant that daytime intravenous infusions could be stopped in all patients. Fecal nitrogen losses were decreased, but overall there was no significant change in fat an caloric absorption. Hormonal stimulated gastric and pancreatic lopase secretions were reduced.	

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Rajendra PK, Pollard, SG / Small bowel transplantation / Current Opinions in Gastroenterology / 2000	review of literature	graft and patient survival	Contraindications: age over 60, cardiopulmonary insufficiency, presence of AIDS, systemic malignancy, life-threatening infections	acute rejection occurs in 73 - 100% of small bowel graft recipients. Overimmunosuppression increases the risk of death caused by severe infections and PTLD. Chronic rejection documented in 8% of cases. GVHD incidence varies between 5 - 16%. Uncontrolled sepsis most frequent cause of death. In 23 - 36% cases at least one episode of CMV. PTLD develops in 10 - 29% cases with 45- 75% being fatal. No difference among three types of grafts. Post '95 patient graft survival is 69/55% 1-year (66/63 w/liver and 63/63 multi) 91% surviving patients discontinue TPN.	failed TPN not defined

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Reyes J, Todo S, Bueno J, et al. / Intestinal transplantation in children: five-year experience / Transplantation Proceedings / 1996	Case review	survival & complications	Between 1990 - 1995, 41 children received 44 intestinal transplants (10 SM alone, 27 SB/L, and 7 MV). 19 males and 22 females with ages ranging between 0.5 and 18 years (means 4.2). 20 grafts included segment of large bowel. All at University of Pittsburgh. 5 were also given unaltered adjuvant donor bone marrow.	24 patients (58.5%) still alive. 20 of which have functioning grafts. Post-transplant hymphoproliferative disease associated with the Epstein-Barr virus has occurred in 11 children (overall incidence of 26.8%), 10 patients presented cytomegalovirus (CMV) disease (24%). A total of 31 surgical/clinical complications occurred in 20 recipients (48%). Of the 41 patients, 36 recipients (39 grafts) experience a mean of 2.6 episodes of rejection. The incidence of rejection when allograft colon was included (90%) was similar to when it was excluded (87.5%). 48% of graft were lost by death or removal. In five cases the failures stemmed from surgical (4) of clinical (1) misadventures. The predominant factor for loss of the remaining 16 grafts were infection (3), PTLD (2), rejection (6) and combination of PTLD and rejection (5). TPN was discontinued an average of 56 days posttransplant.	Small number of cases. Population not Medicare eligible. Single institution.

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Rovera GM, DiMartini A, Schoen RE, etal / Quality of life of patients after intestinal transplantation / Transplantation / 1998	Cohort Study	Responses on the Quality of Life Inventory - 125 questions (emotion state, physical and social functioning, pain and discomfort, relationships, vocations). Change in quality of life was examined logitudinally over a 2-year period.	20 patients (10 intestinal transplant patients, 10 TPN patients). TP patient evaluated at mean time of 2.7 yrs post-transplant and 5.3 yrs post intestinal failure. TPN patients evaluated after mean period of 5.1 years post intestinal failure. Cohorts were sinilar in age, gender, race, social status, education, etiology and duration of disease.	Assessed quality of life was markedly similar between TPN-dependent patients and TP recipients, with significant difference in only 2 of 25 domains, despite the difficult early postoperative course and complex management that accompany intestinal TP.	
Seidner DL, Licata A / Parenteral nutrition-associated metabolic bone disease: pathophysiology, evaluation, and treatment / Nutrition in Clinical Practice / 2000	Opinion			Long-term TPN can cause metabolic bone disease	
Starzl T, Rowe MI, Todo S, et al. / Transplantation of Multiple Abdominal Viscera / Journal of the American Medical Association / 1989	Case study	survival, autopsy, related organ function (liver/pancreas, rejection, infection	2 children with short-gut syndrome and secondary liver failure.	One child died within 30 minutes arrival in intensive care unit post-operatively. The other survived 6 months before dying of an Epstein-Barr virus-associated lymphoproliferative disorder that cause biliary obstruction and lethal sepsis (patient never left hospital).	

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Thompson JS, Langnas AN, Pinch LW et al / Surgical approach to short-bowel syndrome / Annals of Surgery / 1995	Case series		48 adults and 112 children with short bowel syndrome were evaluated ofer a 15-year period.	44% took enteral nutrition alone. 28% were supported by TPN. Various surgical approaches used. The surgical approach to short-bowel syndrome depends on the patient's age, remnant length and caliber, intestinal functions, and TPN related complications. Nontransplant procedures have a role in the treament of selected patients. Intestinal transplantation is emerging as a potential therapy for patients with significant TPN related complications.	

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Todo S, Reyes J, Hiroyuki F, et al. / Outcome analysis of 71 clinical intestinal transplantations / Annals of Surgery / 1995	case reviews	survival and complication. All of the patients were followed until April 6, 1995. Median follow-up was 21 months, ranging from 1.5 months to 57 months. Histopathologic study of endoscope-guided biopsies to confirm rejection. Suspicious skin lesions were biopsied to confirm GVHD	Between May 1990 an February 1995, 71 intestinal transplantations were performed in 66 patients. 37 were children and 29 were adults. 22 received SB alone, 30 SB/L and 11 MVT. Three more recipients were given unaltered donor bone marrow cells perioperatively as a biologic adjuvant.	Of the first 63 recipients, 32 are alive, 28 have function primary grafts and 4 have resumed TPN. Of 35 failed grafts, 10 were lost of mechanical/management errors, 6 to rejection and 19 to infection. To improve outcomes after intestinal transplantation with previous management protocols, it will be necessary to avoid predictably difficult patients, CMV seropositive donors, and inclusion of the graft colon. SB alone succeeded in restoring alimentary function at the lowest rate at all follow-up time after 9 months. Although absorption was never completely normal, 27 of 28 patients still bearing their original grafts are free of intravenous support and some have had to go on obesity-control diets. Four patients underwent retransplantaiton on the same day as primary graft removal, but died 47 - 147 days later. Significantly better graft survival was observed in 34 patients without the colon transplant. Lymphoproliferative disorders occurred in 12 (19%) of patients and caused 8 deaths.	

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Todo S, Tzakis A, Abu-Elmagd K, Reyes J, Starzl TE / Current status of intestinal transplantaton / Advances in Surgery / 1994	Opinion			Complications of TPN include vascular thrombosis, metabolic abnormality, bone disease, cholelithiasis, and ofter lethal sepsis and liver disease. Those with benign intestinal diseases experience 2.6 complication requiring hospitalization per year. In Europe sepsis, major vessel thrombosis and liver failure are ascribed to 28% of the patient deaths under TPN therapy.	